

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,)	
)	
Plaintiff,)	
v.)	C.A. No. 06-230 (GMS)
)	
APOTEX, INC.,)	
)	
Defendant.)	
)	

**MERCK’S REPLY IN SUPPORT OF ITS
MOTION TO STAY FURTHER PROCEEDINGS**

Apotex’s opposition (D.I. 71) to Merck’s motion to stay further proceedings pending the Court’s resolution of subject matter jurisdiction (D.I. 68) treats Merck’s motion as though it were requesting to stay the case indefinitely and does not point to any real prejudice it would suffer from the short-term stay Merck actually seeks. At the same time, Apotex misdirects its argument on the prejudice Merck will suffer if the stay is not granted.

Apotex’s reply also raises three points essentially going to the merits of Merck’s motion to dismiss as to why the Court would be unlikely to grant Merck’s motion to dismiss. Apotex’s arguments are wrong on all counts. And Apotex’s continued effort to paint Merck as a “bad actor,” who somehow has obtained a benefit from this lawsuit, is a baseless distraction from the issues before the Court. If the lawsuit is dismissed as Merck seeks, Merck will be in no different position than it would have been had it never sued at all. But Apotex clearly wanted Merck to sue, and so waited to provide its product information in order to provoke Merck into filing this lawsuit which it then would bootstrap into a merits decision for use against other generics. It is thus

Apotex that is seeking to destroy the delicate balance of the Hatch-Waxman Act and obtain an unfair advantage against the first-filing generics that was not contemplated by the Act.

ARGUMENT

I. A Stay Makes Eminent Sense.

A. Merck Will Be Prejudiced If A Stay Is Not Granted.

Apotex discounts the concerns expressed by Merck as a matter of mere “inconvenience” (p. 2). Merck has already provided the discovery sought by Apotex that is simply a matter of “inconvenience,” such as the substantial document production requested by Apotex. What Merck is concerned about is the burden on individuals (non-lawyers) whose depositions are now being sought and which will require them to take considerable time from their job responsibilities.

Apotex also discounts Merck’s concern that it not be pulled into summary judgment or other merits proceedings before jurisdiction is decided. Apotex asserts that it “is entitled to know why Merck contends that it infringes under the doctrine of equivalents” (p. 12). But as Merck has made abundantly clear, it is not asserting a claim of infringement against Apotex’s filing of the ANDA or against the product of the ANDA. Thus, it will not be contending that Apotex infringes. Apotex gives no basis for its alleged “entitlement” to require Merck to develop a position going to the merits of a claim that Merck will not be asserting against Apotex.¹ Moreover, Apotex does not

¹ Apotex is evidently seeking to bootstrap the court-ordered responses Merck gave to discovery into an alleged claim of infringement by Merck against Apotex. The responses themselves were clear, however, that all Merck was giving was an explanation of what would be a basis for an infringement claim *if* Merck were to be asserting such a claim, which it is *not*.

dispute the fundamental proposition that the Court “cannot consider the merits of the case until it first is assured of its jurisdiction.” *Conoco, Inc. v. Skinner*, 1991 WL 317019 (D. Del. 1991), citing *Allied Poultry Processors Co. v. Polin*, 134 F. Supp. 278, 279 (D. Del. 1955).

B. Apotex Will Not Be Prejudiced By A Stay.

Apotex argues (p. 1) that it will be “severely prejudiced” by a stay because the “longer Merck can prevent a final decision on the merits in favor of Apotex, the longer Merck can delay Apotex’s entry into the market” But Merck’s suggested stay is not likely to delay by much, if at all, any decision on the merits. Rather, Merck’s motion is simply directed to giving the Court an opportunity to decide the threshold issue of subject matter jurisdiction while delaying certain burdensome, remaining proceedings, in particular the depositions Apotex has noticed, Merck’s expert report on validity, and the summary judgment proceedings in May.

Apotex fails to take into account that the Court cannot, in any event, proceed to a judgment without deciding first that it has subject matter jurisdiction. The reality is, if the Court were to grant Merck’s requested stay, and then decide that it has subject matter jurisdiction, it could in short order enter an immediately appealable judgment of noninfringement, because as Merck has made clear, it will not be asserting a claim of infringement against Apotex here regardless of the outcome of the motion to dismiss.² Of course, if the Court were to grant Merck’s requested stay and then decide

² Apotex in several instances states that its goal is to obtain a “nonappealable court decision” prior to August 6, 2007. However, it does not explain how it can do that under any circumstance, given that any decision by this Court, whether on the merits or procedure, would be appealable.

that subject matter jurisdiction does not exist, then Apotex's argument is moot and clearly it will have suffered no prejudice in the form of delay in obtaining a judgment on the merits.

II. Apotex's Arguments As To The Likelihood Of A Grant Of Merck's Motion To Dismiss Are Wrong.

A. MedImmune Does Not Affect This Case.

MedImmune, Inc. v. Genentech, Inc., 549 U.S. ____ (2007) (slip op. attached as Exhibit E to Apotex's response), which deals with the right of a licensee to challenge the patents of a licensor, has not affected the justiciability of cases in which a covenant not to sue has been granted. In *MedImmune*, the Supreme Court determined that, in the context of a patent license, there can exist a justiciable case or controversy between a licensee and a licensor over infringement, validity or enforceability even if the licensee continues to pay royalties.

Specifically, the issue resolved by the Supreme Court was whether a licensee who continues to pay royalties and eliminates the imminent threat of harm loses the right to contest the licensor's patent(s) in federal court. (*MedImmune*, slip op. at 9.) *MedImmune* holds that a licensee is not required to break or terminate a license in order to challenge a patent. The payment of royalties does not extinguish the justiciability of an underlying dispute affecting the legal relationship of the parties. But for the payment of royalties, there was a threatened harm or injury to the licensee. Simply put, there has to exist an actual underlying justiciable dispute.

In this case, Apotex has been granted a covenant not to sue. Merck cannot and will not assert any of the claims of the patents in suit against Apotex in connection

with ANDA 077-982. As far as Apotex is concerned, the patents do not exist and no claims of infringement do, or can, exist. Therefore, there exists no dispute “touching the legal relations of parties having adverse legal interests.” *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937).

B. The 180-Day Exclusivity That Apotex Seeks To Destroy Belongs To Other Generics And Does Not Create A Case Or Controversy Between Merck And Apotex.

Apotex admits in its opposition that its goal is to extinguish the statutorily imposed 180-day exclusivity of other generics. The real parties in interest, the first filers (which appear to be Teva Pharmaceuticals USA, Inc. and Barr Laboratories, Inc., both of which may be entitled to the 180-day exclusivity), are not even parties in this case.

As set out in Merck’s motion to stay the proceedings, Merck filed suit in this action against Apotex in order to preserve its rights when faced with Apotex’s refusal to provide information, as contemplated by the Hatch-Waxman Act, before the filing of suit. After minimal discovery, and at an early point in this action, Merck decided to provide and provided Apotex with a covenant not to sue.

It is now apparent that Apotex’s failure to provide information before the filing of this action was intended to provoke suit so as to allow it to obtain a triggering event that could deprive other generics of their 180-day exclusivity. That exclusivity is one of the many delicate compromises in the Hatch-Waxman Act and one that provides generics that are first ANDA filers with the incentive to incur the cost of challenging the patents of innovator pharmaceutical companies. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

When Watson was trying to achieve a similar result with the expressed purpose of affecting the 180-day exclusivity of first filers, this Court stated:

Thus, the court has no subject matter jurisdiction to declare that ANDA No. 76-768 does not infringe any of the patents in suit. Moreover, given this court's inability and unwillingness to issue advisory opinions, the court cannot declare that the dismissal of Merck's claims has no bearing on whether Watson infringes Merck's patents, or on whether Merck's patents are valid and enforceable.

Merck & Co., Inc. v. Watson Labs., Inc., 2006 WL 1537375, at *3 (D. Del. June 2, 1996).

Ultimately, a patent infringement dispute seeks to adjudicate the rights between a patentee and an accused infringer. In this case, Merck can no longer assert any of the patents in suit against Apotex, and there are no rights affecting the legal relationship between Merck and Apotex that remain to be adjudicated. The remaining dispute, if any, and it may not be a justiciable one, exists among Apotex, the FDA (which administers the statutorily imposed 180-day first filer exclusivity) and the first filer(s).

As the United States Court of Appeals for the D.C. Circuit explained to Apotex a few months ago:

Congress knew that federal courts lack jurisdiction where no case or controversy exists, yet it nonetheless chose to make the exclusivity trigger "a decision of a court . . . holding the [challenged] patent . . . to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv). Congress's regulatory scheme thus depends in large measure on whether courts can maintain jurisdiction over patent suits.

Apotex, Inc. v. FDA, 449 F.3d 1249, 1253 (D.C. Cir. 2006). It is in that case that Apotex acknowledged and advanced the proposition that a generic manufacturer cannot maintain an action against a patent holder who covenants not to sue for infringement. *Id.*

Apotex's attempt to disturb the Hatch-Waxman framework is not a justiciable controversy between Merck and Apotex. "To invoke the jurisdiction of a federal court, a litigant must have suffered, or be threatened with, an actual injury

traceable to the defendant.” *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477 (1990). In this case, the first filers’ 180-day exclusivity is not the result of Merck’s filing this suit; rather that exclusivity is statutorily imposed and existed *before* Merck sued Apotex.³

C. Apotex’s Claim That Its Customers May Be Harmed Is Wrong.

Finally, Apotex argues that the covenant not to sue does not protect Apotex’s customers. Though Merck disagrees with Apotex’s assertion, this is a red herring given that Merck has stated to Apotex that it would be willing to accommodate Apotex’s concerns on this ground. Apotex has failed to come forward with any concrete position or suggestion as to how it can be assured that its customers would not be subjected to any liability from the patents in suit.

³ Apotex is well aware of this. After Glaxo did not sue Apotex for an ANDA filing, Apotex itself brought a declaratory judgment action for the purpose of disturbing a first filer’s 180-day exclusivity. (*See Apotex v. Glaxo* Complaint attached as Exhibit B to Merck motion to stay proceedings at 17 (¶80)).

CONCLUSION

For the foregoing reasons and the reasons set forth in Merck's motion to stay, Merck asks that the Court grant a stay of the proceedings until the Court decides the issue of subject matter jurisdiction.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

Mary B. Graham (#2256)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
302.658.9200

OF COUNSEL:

Attorneys for Merck & Co., Inc.

John F. Lynch
HOWREY, LLP
1111 Louisiana, 25th Floor
Houston, TX 77002-5242
650.463.8100

Nicolas G. Barzoukas
Suzy S. Harbison
Jason C. Abair
WEIL, GOTSHAL & MANGES
700 Louisiana, Suite 1600
Houston, TX 77002
713.546.5000

Paul D. Matukaitis
Edward W. Murray
Gerard M. Devlin
MERCK & CO., INC.
126 E. Lincoln Avenue RY28-320
Rahway, NJ 07065-0907
732.594.4000

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CERTIFICATE OF SERVICE

I hereby certify that on February 16, 2007, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 North Market Street
Wilmington, DE 19899

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on February 16, 2007 upon the following individuals in the manner indicated:

BY E-MAIL AND HAND DELIVERY

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 North Market Street
Wilmington, DE 19899

BY E-MAIL

Louise Walsh, Esquire
WELSH & KATZ, LTD.
120 South Riverside Plaza; 22nd Floor
Chicago, IL 60606

/s/ Mary B. Graham

Mary B. Graham (#2256)